No. 95-477

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

NOVOPHARM LTD.,

Petitioner,

—v.—

GLAXO, INC. and GLAXO GROUP LIMITED,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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COUNTER STATEMENT OF QUESTIONS PRESENTED

1. Were the District Court and the Court of Appeals for the Federal Circuit correct in finding that the best mode requirement of 35 U.S.C. § 112 is not violated when the *inventor* (vis-a-vis others at the corporate assignee) did not know of a preferred way of formulating the active ingredient for an anti-ulcer medicine (the claimed subject matter) into tablets when:

(i) the *statute* by its express terms is directed to only the inventor's knowledge*;

(ii) the comparable provisions of prior statutes were specific only to the *inventor's* knowledge (Court of Appeals Decision at A.13a** and its f.n. 6);

(iii) Repeated authorities had explained and held that the best mode requirement addresses the subjective intent of *the inventor* (A.11a-15a); and

(iv) Congress "was aware of the differences between inventors and assignees", *see* 35 U.S.C. §§ 100(d) and 152, and it specifically limited the best mode required to that contemplated by the inventor. The Courts "have no authority to extend the requirements beyond the limits set by Congress." (A.11a-19a).

2. Was petitioner Novopharm denied due process when the Court of Appeals referred to the Declaration of the inventor of the patent in suit, Dr. Derek Crookes, filed in opposition to a pretrial motion of Novopharm when:

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* 35 U.S.C. § 112 provides in pertinent part:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, . . . and shall set forth the best mode contemplated by the *inventor* of carrying out his invention." (emphasis added).

** References in this form are to the Appendix attached to Novopharm's Petition for a Writ of Certiorari.

(i) *Petitioner Novopharm* raised the Declaration in *its* brief on appeal before the Federal Circuit, and that Court's Opinion corrected/disagreed with the way Novopharm characterized the substance of the Declaration;

(ii) The Declaration did not form any part of the District Court's decision of the case; and

(iii) The Federal Circuit's discussion of the Declaration is not a necessary part of its decision of the case.

3. Was petitioner Novopharm denied due process when the District Court denied Novopharm a deposition of the inventor of the patent in suit with respect to the supposed best mode violation when:

(i) Novopharm noticed the deposition for the weekend before trial—after having had the underlying documents supporting its supposed best mode violation for over two months;

(ii) Novopharm's notice of deposition in the United States of the United Kingdom resident inventor was in clear violation of Rule 26(a), 34(b), and 45(c)(3)(A)(ii) of the Federal Rules of Civil Procedure.

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INTRODUCTION

Respondents, Glaxo, Inc. and Glaxo Group Limited (hereinafter referred to collectively as "Glaxo") submit this Brief in Opposition to the Petition for Writ Of Certiorari submitted by Novopharm Ltd. (hereinafter referred to as "Novopharm").

SUMMARY OF REASONS FOR DENYING NOVOPHARM'S PETITION FOR WRIT OF CERTIORARI

1. The District Court and Court of Appeals for the Federal Circuit correctly applied the explicit provisions of 35 U.S.C. § 112, first paragraph, and a significant body of consistent authority construing that statutory provision, in requiring that an inventor alone must know of and conceal a "best mode" for practicing his invention before the statute is violated.

2. Petitioner-defendant Novopharm was not denied due process:

(a) in being denied a deposition notice only the weekend before trial after being possessed of documents which raised the issues sought to be pursued months prior, and where the deposition of the United Kingdom resident was noticed for a situs violative of Rules 26(a), 34(b) and 45(c)(3)(A)(ii) of the Federal Rules of Civil Procedure; and

(b) by reference in the Federal Circuit's affirming opinion to a Declaration not in the trial record where no use at all was made of that Declaration by the District Court in deciding the case, where the Federal Court disagreed with *Petitioner's* characterization of the Declaration in *Petitioner's* brief on appeal, and where the reference is not essential to the Federal Circuit's affirmance.

COUNTER STATEMENT OF THE CASE

Respondent-plaintiff Glaxo Group Ltd., a major United Kingdom-based pharmaceutical concern, is the owner of United States Patent No. 4,521,431 ("the '431 patent") covering a particular crystalline form of a chemical compound called ranitidine hydrochloride.[1] Respondent-plaintiff Glaxo Inc. is the exclusive U.S. licensee of the '431 patent.

Petitioner-defendant Novopharm, a Canadian generic drug vendor, infringed the '431 patent by filing an Abbreviated New Drug Application (ANDA) with the Federal Food and Drug Administration seeking to market ranitidine hydrochloride beginning in 1995 before the '431 patent expires. Plaintiffs (hereinafter referred to collectively as "Glaxo") then filed this action requesting an injunction barring further infringement by Novopharm.

Novopharm filed an Answer asserting a number of affirmative invalidity defenses including obviousness, anticipation, and a violation of the best mode requirement. To extricate itself from jointly litigating with another Canadian generic drug company, a defendant in an earlier filed case also seeking to invalidate the '431 patent under the Waxman-Hatch Act, and to obtain an expedited and earlier trial, Novopharm waived all affirmative defenses except anticipation.[2] As Novopharm characterized its "one issue", "streamlined" case:

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[1] Glaxo markets the patented polymorphic form of ranitidine hydrochloride as an anti-ulcer medication under the brand name Zantac®. Zantac® is the world's largest selling prescription drug.

[2] This strategy appears to be driven by Novopharm's desire to deny Genpharm Pharmaceuticals (the other generic drug company contesting '431) the possibility of completing a trial on the '431 patent and obtaining a judgment before Novopharm. Novopharm hoped thus to prevent Genpharm from claiming the exclusive right to market generic ranitidine hydrochloride for the six month period provided to Genpharm under 21 U.S.C. § 355(j)(4)(B)(iv) if Genpharm invalidated the '431 patent before Novopharm did.

> Novopharm's defense to Glaxo's infringement charge is based on invalidity of the claims of the '431 patent for double patenting under 35 U.S.C. § 101 and/or anticipation under 35 U.S.C. § 102(a), (b) and (e). Each of these defenses, however, turns on a single factual issue—whether when Example 32 of Glaxo's U.S. Patent 4,128,658 ("the '658 patent") is performed, the ranitidine hydrochloride claimed in claims 1 and 2 of the '431 patent is produced. If that question is answered in the affirmative, Novopharm wins; if it is not, Glaxo wins.

(Emphasis added).

This "one issue" case didn't last long in that posture. Novopharm quickly realized from the Glaxo documents obtained in its discovery that Example 32 was not a theoretical or paper example but, rather, represented actual experience, and that the Example had *not* produced the crystalline compound of the '431 claims, thus eviscerating Novopharm's anticipation defense. Novopharm's prospects on "inherency" invalidation were thus dim. Novopharm thereafter amended its defenses—first to add supposed inequitable conduct, and then to reintroduce best mode.

The case was tried in a two week bench trial beginning August 9, 1993 on the three affirmative patent invalidity defenses. Following Novopharm's evidence in its case-in-chief, Glaxo moved under Rule 52(c), Fed.R.Civ.P., *inter alia*, for a dismissal of the best mode defense. The District Court decided that it would:

> withdraw the best mode defense from the trial and make a ruling on that as a matter of law.
>
> I need an opportunity to further examine the law. If the defendants—if the plaintiffs are correct with respect to the claims and the knowledge of the inventor, then they would be entitled to a judgment as a matter of law on the facts in this case, and I just need to decide and resolve the status of the law in that regard.

After trial, the District Court ruled against Novopharm on each defense, and enjoined prospective infringement.

The Court of Appeals for the Federal Circuit affirmed, rejecting the best mode and other affirmative invalidity defenses. 52 F.3d 1043, at 1049-1052 (1995) (Judge Mayer dissenting). Novopharm's Petition for Rehearing with a Suggestion for Rehearing In Banc—raising the issues it presses here—was denied without dissent. (A. 59a-60a).

COUNTER STATEMENT OF FACTS

A. United States Patent No. 4,521,431 In Suit And Its Infringement

The '431 patent in suit covers a particular, newly created crystalline polymorphic[3] form ("Form 2") of the *per se* previously known chemical molecule ranitidine hydrochloride. Form 2 ranitidine hydrochloride was invented by a Glaxo chemist Dr. Derek Crookes. The patented Form 2 polymorph is the active drug substance in a medicine sold under the trademark "Zantac"®, used to treat conditions relieved by lowering gastric acidity. Its main use is for treatment of gastric and peptic ulcers. There are other substantial medical indications. The drug functions as an H_2-antagonist; i.e., it inhibits the histamine-induced secretion of gastric acid in the stomach. Claims 1 and 2 of the '431 patent are specific to the Form 2 ranitidine hydrochloride polymorph active drug substance.

Novopharm filed an Abbreviated New Drug Application ("ANDA") seeking the approval of the Federal Food and Drug Administration to market Form 2 ranitidine hydrochloride on December 5, 1995 - before the '431 patent expires. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is a statutory act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

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[3] Certain crystals can exist with their constituent repeating chemical molecules arranged in the crystalline lattice in different ways. Each such different crystalline structure is called a "polymorph".

Novopharm admitted infringement of claims 1 and 2 of the '431 patent by formal Rule 36 Fed.R.Civ.P. judicial admission.

B. The Azeotrope Granulation "Best Mode" Facts

Novopharm's best mode defense was withdrawn from presentation of evidence by the District Court at the conclusion of petitioner's case in response to Glaxo's motion to dismiss under Rule 52(c), Fed.R.Civ.P. (Please see, p. 3-4, *supra*). We thus discuss the limited trial facts Novopharm presented on point - and what was lacking in its presentation.

a. Substantive Matters

(i) The Trial Evidence On "Best Mode"

The application leading to the '431 patent was filed and prosecuted for years with only two claims, the claims ultimately issuing as claims 1 and 2 of the patent in suit.[4] These are both for the Form 2 ranitidine hydrochloride active drug substance (only). The sole inventor of the claimed Form 2 ranitidine hydrochloride was Dr. Derek Crookes who discovered it.

When the application was filed, some scientists at Glaxo (only Mr. Collin is identified in the record) knew of an azeotrope granulation process which was preferred when ranitidine hydrochloride was formulated into tablets with various excipients.[5]

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[4] Claim 2 was originally independent. It was amended during prosecution to depend from claim 1.

[5] Ranitidine hydrochloride is a relatively light material ("low bulk density"). When the material was given to the Glaxo Pharmacy Department, Glaxo scientists in that Department charged with combining the ranitidine hydrochloride with various fillers, binders and carrier, to form commercial products chose an azeotroping process to granulate the active drug substance (granulation in one way or another is common to most tableting processes and has been for years). This process increased the bulk density of the material, making it easier to dispense the active ingredient accurately when manufacturing tablets.

Mr. Graham Brereton, the Glaxo U.K. corporate patent staff member who initially worked on patenting the Form 2 invention at Glaxo, knew of the azeotrope granulation process. So did the United Kingdom Chartered Patent Agent who corresponded with Mr. Brereton, Mr. Marchant of the firm of Elkington & Fife, who was responsible for worldwide international patent filings for the Form 2 subject matter.

Messrs. Brereton and Marchant reasoned that there would be no best mode problem in the United States with respect to claims to the Form 2 ranitidine hydrochloride active ingredient *per se* if azeotrope granulation was not disclosed in the application leading to the '431 patent. They assumed that there would be a problem if pharmaceutical preparations (e.g., tablets) were claimed. They did not have in mind the United States requirement for knowledge by the *inventor* before a best mode issue arises. No United States attorney was consulted on the subject.

This all proceeded without the knowledge or participation of the inventor Dr. Crookes. The *only* evidence in this record is that Dr. Crookes simply did not know of the azeotrope-granulation process.

(ii) Factual Areas Not Treated By Novopharm's "Best Mode" Trial Evidence

There is nothing in the trial record to suggest any involvement or knowledge of inventor Crookes in the field of pharmaceutical formulation for any purpose, and certainly not for the formulation of administrable medicines from the Form 2 ranitidine hydrochloride active drug substance.[6] Rather, Dr. Crookes was charged with replicating chemical batches of the ranitidine hydrochloride active ingredient, and with developing a chemical recrystallization process. Both of these

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[6] Pharmacy—the art and science of processing active drug substances, stabilizers, buffers, and other excipients into administrable medicines—is a recognized field unto itself, with its own professional associations, journals and the like.

responsibilities *ended* when the active drug substance was created, leaving to others of another technical discipline the task of formulating the ranitidine hydrochloride raw chemical into administrable products.

There is nothing in the record from which the District Court as trier of fact could conclude that Dr. Crookes had any role in or knowledge of the azeotrope granulation process to tablet Form 2 (or any form) of ranitidine hydrochloride. The District Court found there was no evidence from which to find such knowledge reposing with Dr. Crookes. (A. 56a). The Federal Circuit agreed. (A.16a).

There is also no evidence in the record - none - of any attempt or plan to isolate or freeze out Dr. Crookes from knowledge or participation with tableting. Indeed, Dr. Crookes had left ranitidine work for other responsibilities before the United States filing was being prepared or prosecuted.

We note the above facts presented in petitioner Novopharm's case at trial—not from Glaxo's case at trial. The reason, again, is that the "best mode" defense was withdrawn under Rule 52(c) before Glaxo would have been called upon to respond.

b. Novopharm's Belated Discovery Attempts

This litigation began with Novopharm pleading an affirmative "best mode" invalidity defense. Novopharm then decided not to pursue it, electing instead to proceed on a "streamlined", anticipation-only basis to reach trial before Genpharm. This strategy changed, however, with the recognition that its chosen anticipation defense came a cropper. (Please see, p. 3, *supra*).

On *June 2*, 1993 - over two months before trial - Novopharm received *all* of the documents upon which it relied for the best mode defense. Novopharm complains here that it was wrongfully denied the deposition of Dr. Crookes

on the best mode defense. The reason it was denied the deposition was that Novopharm didn't ask for it in a timely, or anything like a timely, manner; and Novopharm didn't notice the deposition in a proper forum.

This case had long been set for trial beginning August 9, 1993. Novopharm had made several attempts to adjourn the trial, which were denied. It was clear under North Carolina practice and District Court Judge Boyle's rulings that the trial date was real.

The *August 9th* imminent trial date notwithstanding, Novopharm did not notice Dr. Crookes' deposition until *August 5-7*, 1993. That is literally the weekend before trial was to begin. Rather than seek such discovery after receiving the documents it relies upon for its best mode defense, Novopharm had proceeded by motion for summary judgment on best mode grounds without having any information that Dr. Crookes had knowledge of the "best mode". Instead, Novopharm chose to proceed on its theory that "best mode" knowledge of others at the corporate assignee Glaxo sufficed for a best mode defense . Moreover, when Novopharm finally did request Dr. Crookes' deposition, Novopharm noticed Dr. Crookes, a resident of the United Kingdom, for deposition in Elizabeth City, North Carolina.[7,8] Elizabeth City, North Carolina is far more than 100 miles from the U.K. The Notice was urged to be improper under Rules 26(a), 34(b) and 45(c)(3)(A)(ii), Fed.R.Civ.P. The Notice was served days after the District Court had already denied Novopharm's frenetic attempts to obtain the compulsory presence in North Carolina

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[7] During the years of discovery, Glaxo had voluntarily produced *all* prior witnesses requested by Novopharm in New York at the offices of Glaxo's trial counsel.

[8] Only Novopharm can speak to why it waited until the weekend before trial to notice Dr. Crookes, and violated the Rules in choosing the forum. Our belief is that the clear purport of the Declaration Dr. Crookes submitted opposing Novopharm's motion for summary judgment on best mode grounds demonstrated to Novopharm that there was little prospect that such a deposition would be useful.

of other Glaxo U.K.-based employees on the same Rule 45 grounds. The District Court denied Novopharm's efforts to compel this discovery.

ARGUMENT

Point I. There Was No Best Mode Violation

(i) Novopharm's Best Mode Defense Lacks Merit—And There Was No Failure Of Procedural Due Process

"Best mode" is an issue of fact. *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991), *cert. denied*, 112 S.Ct. 169, 116 L.Ed.2d 132 (1991). Petitioner Novopharm had the burden of proving the facts of this affirmative defense - and proving it by clear and convincing evidence. *Scripps Clinic & Research Foundation* v. *Genentech, Inc.*, 927 F.2d 1565, 1578 (Fed. Cir. 1991); *Engel Industries, Inc.* v. *Lockformer Co.*, 946 F.2d 1528, 1531 (Fed. Cir. 1991).

During Novopharm's case-in-chief at trial, it produced *no* evidence (much less clear and convincing evidence) from which the District Court could conclude that Dr. Derek Crookes, the *inventor* of U.S. Patent No. 4,521,431 in suit, knew of the azeotroping process used during the formulation of the ranitidine hydrochloride active drug substance into tablets, or any special benefits of that process. (See, pp. 6-7, *supra*). Accordingly, the District Court correctly concluded that it could not "find as a fact Crookes knew azeotroping was the preferred mode or attempted to conceal such preferred mode in the '431 patent application."[9] 830 F.Supp. 871, at 881

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[9] Novopharm's only basis for claiming the finding was clearly erroneous is that knowledge by Crookes of azeotrope granulation at the time of filing should be inferred because others at Glaxo had such knowledge. There is absolutely no basis for this inference, and the trial court correctly refused to make it.

(1993). The Federal Circuit agreed. (A.16a). Petitioner Novopharm also failed to produce *any* evidence (much less clear and convincing evidence) of any purposeful scheme at Glaxo to isolate or freeze Dr. Crookes out of knowledge concerning the azeotrope granulation process or its benefits.

Novopharm urges that the record is devoid of evidence of Dr. Crookes' knowledge of the best mode because Glaxo and the District Court improperly denied Novopharm discovery on the issue. However, Novopharm's deposition discovery attempt was belated because Novopharm had dropped the defense after having pleaded it at the very beginning of the case; the discovery attempt was belated because Novopharm pursued summary judgment on its erroneous assumption that Glaxo's corporate knowledge sufficed for "best mode" purposes without also pursuing discovery on Dr. Crookes' knowledge; and when Novopharm finally attempted to obtain a deposition on the eve of trial, the discovery attempt was improper under Rules 26(a), 34(b) and 45(c)(3)(A)(ii) because the situs chosen for the deposition was improper.[10] (Please see, pp. 3-4, 8-9 *supra* regarding Novopharm's tactical summary judgment choice and attribution argument, and its eve-of-trial shift of approach.) This out-of-time, out-of-place discovery was properly denied by the District Court. Novopharm makes no showing that it was an abuse of discretion, much less a denial of due process.[11]

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[10] *Farmer* v. *Arabian American Oil Co.*, 379 U.S. 27, 231-32, 13 L.Ed.2d 248, 85 S.Ct. 411 (1964); *St. Paul Fire & Marine Insurance Company* v. *Royal Insurance Company of America*, 1993 U.S. Dist. LEXIS 9415 (S.D.N.Y. July 9, 1993); *Brockton Savings Bank* v. *Peat, Marwick, Mitchell & Co.*, 771 F.2d 5, 10 (1st Cir. 1985), *cert. denied*, 475 U.S. 1018, 106 S.Ct. 1204, 89 L.Ed.2d 317 (1986); *Cleveland* v. *Palmby*, 75 F.R.D. 654 (W.D.Ok. 1977); *Smith* v. *Bic Corp.*, 121 F.R.D. 235, 245 (E.D.Pa. 1988), *aff'd. in relevant part*, 869 F.2d 194 (3rd Cir. 1989); *Hecht* v. *Don Mowry Flexo Parts, Inc.*, 111 F.R.D. 6, 11 (N.D.Ill. 1986).

[11] *Serrano-Perez* v. *FMC Corp.*, 985 F.2d 625, 627-28 (1st Cir. 1993); *Folmar* v. *American Health and Life Ins. Co.*, 91 F.R.D. 22, 25-26 (E.D.Tenn. 1981); *Havee* v. *Belk*, 775 F.2d 1209, 1223 (4th Cir. 1985).

Following Novopharm's evidence, the District Court withdrew the best mode defense after Glaxo's motion to dismiss under Rule 52(c), and there was no presentation by Glaxo on the point.

(ii) The Statute Is Clear; Means What It Says; And Requires The Best Mode Be Known To The Inventor - There Was No Best Mode Violation

The patent statute requires that the patent application specification "set forth the best mode contemplated by the *inventor* of carrying out his invention" (emphasis added) (See the first footnote on page i, *supra*.). A litany of authority prior to this case made clear that a best mode analysis addresses *only* the subjective knowledge of the inventor. *Texas Instruments Inc.* v. *U.S. Int'l. Trade Com'n*, 871 F.2d 1054, 1061 (Fed. Cir. 1989); *Chemcast Corp.* v. *Arco Industries Corp.*, 913 F.2d 923, 927-28 (Fed. Cir. 1990); *Engel Industries, Inc.* v. *Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991); *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1209-10 (Fed. Cir. 1991); *Spectra-Physics, Inc.* v. *Coherent, Inc.*, 827 F.2d 1524, 1532 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954, 108 S.Ct. 346, 98 L.Ed.2d 372 (1987); *Hewlett-Packard Co.* v. *Bausch & Lomb Inc.*, 722 F.Supp. 595 (N.D.Cal. 1989), *aff'd.*, 909 F.2d 1464 (Fed. Cir. 1990); *Studiengesellschaft Kohle* v. *Eastman Kodak Co.*, 616 F.2d 1315, 1340 (5th Cir. 1980), *cert. denied*, 449 U.S. 1014, 101 S.Ct. 573, 66 L.Ed.2d 473 (1980); *Honeywell Inc.* v. *Minolta Camera Co. Ltd.*, 1991 U.S. Dist. LEXIS 4222 (D.N.J. 1991); R.L. Harmon, *Patents and the Federal Circuit*, 2nd Edition, § 3.53 (BNA 1991); K. Adamo, "What's Better, What's Best - The Best Mode Requirement in US Patent Practice", *Journal of Patent & Trademark Office Society*, November 1991, pp. 814-815.

The Federal Circuit Opinion in this case concurred with this body of settled law, noting that "the statutory language could not be clearer". (A.13a). The Court below reinforced this

view by tracing the requirement for knowledge by the *inventor* in prior Patent Acts (A. 13a); in the official Commentary on the New Patent Act, 35 USCA 1, 25 (1954) (A.13a); and in an extensive line of cases requiring the subjective intention of an *inventor* to conceal a "best mode" before a violation occurs. (A. 13a-16a).

The operative rule of law has been decided and consistently applied - and accords with the language of the statute which Congress has adopted.[12] We respectfully urge that the law requires judgment for Glaxo on the issue for failure of proof of knowledge by the inventor Crookes[13], and that the District Court and Court of Appeals were correct.

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[12] Novopharm's Petition cites *CPC International, Inc.* v. *Archer Daniels Midland Company*, Nos. 94-1045, 94-1060 (Fed. Cir. July 11, 1994) (A. 59a-69a) as its only supposed substantive authority in disagreement with all of this. *CPC* was a *per curiam* affirmance (the day following oral argument) where the prevailing accused infringer pressed six bases for affirmance of the decision in its favor below. The *CPC* affirmance was designated non-precedential under the Federal Circuit's Rule 47.6(d). 31 F.3d 1176 (Fed.Cir. 1994). That Rule cautions that "opinions and orders so designated shall not be employed or cited as precedent". Novopharm ignored that Rule when repeatedly urging *CPC*, unsuccessfully, before the Federal Circuit; and ignores the Rule here. There is no division in the Federal Circuit regarding the requirement for inventor's knowledge—there was no dissent in the denial of Novopharm's suggestion for a rehearing *in banc* on the issue presented by *CPC*.

[13] Petitioner Novopharm's attempt to raise a negative inference from the fact that Derek Crookes did not testify at the trial on "best mode" should be rejected. As Glaxo had previously advised the Court, Glaxo had intended to call Dr. Crookes during its rebuttal case on the best mode issue, but the issue was withdrawn before Glaxo's rebuttal case began. Negative inferences cannot be drawn when, as was the case here, there is no *opportunity* to offer testimony. *Cf. Savard* v. *Marine Contracting Inc.*, 471 F.2d 536, 542 (2d Cir. 1972), *cert. denied*, 412 U.S. 943, 93 S.Ct. 2778, 37 L.Ed.2d 404 (1973) (no inference where evidence not within party's control) 2 Wigmore, Evidence § 290 p. 218-219 (Chadbourne rev. 1979) (until proponent has proven its case, failure to produce evidence cannot afford any inference). Moreover, inferences, negative or otherwise, do not suffice for even a *prima facie*, much less a clear and convincing, case. *Layne* v. *Vinzant*, 657 F.2d 468, 472 (1st Cir. 1981); *El*

Point II. There Was No Denial Of Due Process Concerning The Crookes Declaration

As part of its opposition to petitioner Novopharm's motion for summary judgment before the District Court, Glaxo submitted a Declaration of inventor Crookes that he was not aware of the "best mode" azeotrope granulation process. (See, pp 6-7 *supra*; the Crookes Declaration is reproduced in a Supplemental Appendix, attached to this Brief.) Novopharm's thesis in its Petition is that the Federal Circuit denied Novopharm due process in referring to the Crookes Declaration (A.16a).

There was no due process violation regarding the Crookes Declaration by the District Court. The District Court reviewed the evidence submitted by Novopharm during its opposition case-in-chief. The Court noted that the "only evidence Novopharm presented on its best mode defense was the testimony of Graham George Brereton and concluded that there was *no* evidence that Dr. Crookes was aware of the best mode azeotrope granulation process. The trial judge made *no* mention of the Crookes Declaration and it formed no part of his decision.

There was similarly no due process violation by the Federal Circuit. The Courts of Appeals review judgments below for error, *Torrington Co.* v. *Local Union 590 of Int'l. Union*, 803 F.2d 927, 932 (7th Cir. 1986); *Worsham* v. *Duke*, 220 F.2d 506, 509 (6th Cir. 1955), and the District Court could not have committed error since it did not in any way refer to the Crookes Declaration in its decision making process.

For its part, the Federal Circuit's affirmance rested upon the failure of Novopharm to sustain its burden of proving the

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Ranco Inc. v. *First National Bank of Nevada*, 406 F.2d 1205, 1215 (9th Cir. 1968), *cert. denied*, 396 U.S. 875 (1969); *United States* v. *Roberson*, 233 F.2d 517, 519 (5th Cir. 1956). The District Court and Court of Appeals were invited by Novopharm to make the negative inference, but correctly decided not to do so.

supposed "best mode" defense, not on Glaxo's demonstrating that the defense lacked merit, and it was not Glaxo's burden to do so. The Court of Appeals Opinion found that the statutory language (35 U.S.C. § 112, first paragraph) "could not be clearer" that a best mode inquiry is directed to the knowledge of the *inventor* (A. 12a-15a) and then applied the law to the trial evidence:

> There is simply no evidence in the record before us, indeed Novopharm points to none, that the inventor of the '431 patent knew of and concealed the azeotroping process when his application was filed.[14] (A. 16a).

The District Court's rejection of the best mode defense was affirmed on this basis. Accordingly, there was no due process violation here.

* * *

Indeed, it is at least curious that *Novopharm* even raises here the propriety of the Federal Circuit's discussion of the Crookes Declaration (as they also did unsuccessfully with the Federal Circuit upon Petition for Reconsideration). The Crookes Declaration disclaiming knowledge of azeotrope granulation was raised to the Federal Circuit by *petitioner Novopharm*. Page 27 of *Novopharm's* Brief on Appeal below made reference to the Declaration and pejoratively characterized it as an "evasive affidavit [sic]". Novopharm's Reply Brief (page 5) also discussed the Declaration. Novopharm should not be heard to complain that the Federal Court's Opinion (A. 16a.) disagreed with Novopharm on a matter *it* chose to bring into the Appeal. The Court of Appeal's reading of the Declaration that Dr. Crookes did not know of azeotrope granulation (unlike the way *Novopharm* had characterized it

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[14] Even at this belated point in the proceedings Novopharm does not point to any record evidence that Dr. Crookes knew of the azeotrope granulation process.

in its opening Brief on appeal) in any event is not a necessary part of its affirmance.[15] As explicitly observed by both the Federal Circuit and the District Court, Novopharm failed on its best mode defense because it failed in *its* burden of proving that Dr. Crookes knew of the process.[16]

CONCLUSION

For the reasons stated above, Respondents Glaxo, Inc. and Glaxo Group Limited respectfully urge that Novopharm's Petition for Writ of Certiorari be denied.

Dated: October 19, 1995

Respectfully submitted,

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[15] If it mattered, the *only* record evidence on Dr. Crookes' knowledge of the azeotrope granulation process is that he did not know. (A. 56a).

[16] We also note that the azeotrope granulation process for making tablets is not invoked as any part of the manufacture of the Form 2 ranitidine hydrochloride which is the subject of claims 1 and 2. Even *had* Dr. Crookes known of this subject matter, Glaxo urges that there would be no best mode violation of these claims. The issue was expressly reserved in footnote 7 of the Federal Circuit's Opinion. (A. 16a)

APPENDIX

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
RALEIGH DIVISION

Civil Action No. 91-759-CIV-5-B0

GLAXO INC. and GLAXO GROUP LIMITED,

Plaintiffs,

—v.—

NOVOPHARM LTD.,

Defendant.

DECLARATION OF DR. DEREK CROOKES IN OPPOSITION TO DEFENDANT NOVOPHARM'S MOTION FOR SUMMARY JUDGMENT ON SUPPOSED BEST MODE PATENT INVALIDITY GROUNDS

I, Derek Crookes, a British subject and a resident of the United Kingdom, declare upon knowledge, information and belief as follows:

1. I am employed by Glaxo Group Research, an affiliate of Glaxo Group Limited, a co-plaintiff in this litigation. I am the sole inventor of United States Patent No. 4,521,431. I was awarded a Ph.D degree in Chemistry in 1978 by Manchester University.

2. I joined Glaxo as a member of its Chemical Development Department in 1978. I worked on the preparation of ranitidine hydrochloride at Glaxo between September 1979 and November 1980, and not thereafter, with the sole exception of my

involvement with this litigation after its commencement in 1991.

3. Before I joined the ranitidine hydrochloride project in September, 1979, and prior to any work by me, the earlier crystalline form of ranitidine hydrochloride (now called Form 1) had already been synthesized as of 1977; and the generic ranitidine hydrochloride molecule had been patented (United States Patent No. 4,128,658 issued December 5, 1978).

4. Beginning in September 1979, part of my assigned responsibility was to produce batches of bulk ranitidine hydrochloride to serve as an active drug substance. The material which I initially produced was of the crystalline form now known as Form 1 ranitidine hydrochloride. I was also charged with the identification and scale-up of possible alternative synthetic routes which might lead to the Form 1 ranitidine hydrochloride active drug substance.

5. The bulk active material I produced was provided to Glaxo's Pharmacy Department. Pharmacy's job, in turn, was to formulate the ranitidine hydrochloride active ingredient into medicinal products; i.e., to develop methods to process the ranitidine hydrochloride active drug substance and various excipients into medically administrable tablets, syrups, injectables and other formulations. Pharmacy supplied yet further groups such as Glaxo's Pathology and Clinical Departments with their requirements of formulated product for whatever testing they deemed appropriate.

6. On April 15, 1980, without prior intention to do so, I invented the Form 2 polymorph of ranitidine hydrochloride while preparing a batch of ranitidine hydrochloride known as 3B13. By inspection I judged the ranitidine hydrochloride material prepared in batch 3B13 to be different from earlier batches. Both infra-red and x-ray powder diffraction measurements were made of the ranitidine hydrochloride I made in batch 3B13. Each of these measurements confirmed that I had prepared a different crystalline polymorph which has now come to be known as Form 2 ranitidine hydrochloride.

7. Several hundreds of kilograms of ranitidine hydrochloride (Form 1) had been processed by the Pharmacy Department prior to my invention of the Form 2 polymorph of ranitidine hydrochloride on April 15, 1980. I produced ranitidine hydrochloride active drug substance (either Form 1 or Form 2) as required from time to time in batches of approximate size 20 to 60 kilograms, and supplied the active drug substance to Pharmacy.

8. As I viewed matters - both when I was active on the ranitidine hydrochloride project in 1979-1980, and currently - Pharmacy Department's work, skills and knowledge were different from mine; and their responsibilities were different from mine.

9. I - the inventor of the subject matter underlying U.S. Patent No. 4,521,431 - did not participate in the development of the process or processes by which the active drug substance Form 2 ranitidine hydrochloride was processed with excipients into administrable medicine of any form. I did not know of any azeotroping of ranitidine hydrochloride, or of its benefits, prior to commencement of this litigation. I did not—indeed, could not—consider the azeotrope process a "best mode" of making ranitidine hydrochloride tablets at the time of filing any patent application. I did not—indeed, could not—consider azeotroping the best mode of carrying out my invention at any time while the '431 patent was pending.

10. I knew that Pharmacy was using a granulation process to make tablets from the ranitidine hydrochloride active drug substance I provided to them. It was my understanding in 1979-1980 - and it is my understanding now - that granulation is a process used when formulating tablets from a great many, perhaps most, active drug substances. I did not know the specific details of the granulation process or processes to which Pharmacy put ranitidine hydrochloride. At all times prior to this litigation, I believed that whatever granulation process or processes Pharmacy was using were simply conventional. I believed that the process or processes did not differ from

conventional granulation, or give rise to any benefit not common to conventional granulation.

11. I have been advised that patent applications were filed on the azeotrope process for ranitidine hydrochloride. I did none of the work which underlies those patent applications; I was not an inventor or co-inventor of that work; I did not know of that work until after this litigation commenced.

I declare further that all statements made herein to my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: July 8, 1993

/s/ DEREK CROOKES
Dr. Derek Crookes